

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 9

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

JAN 25 2002

Ex parte RALPH A. NELSON, PATRICIA G. MIERS,
AND KENNETH L. RINEHART

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCE

Appeal No. 2001-1750
Application No. 08/833,096

ON BRIEF

Before WINTERS, MILLS, and SCHEINER, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-21, 24-33, 44-45, 49-51 and 63-66, the claims on appeal in the present application.

A complete copy of the claims on appeal as provided by the appellants with their Brief is attached to this opinion. Claim 64, missing from the appellants Brief, and as provided by the examiner in the Answer, is set forth below.

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64. A pharmacological composition of matter comprising the blood or urine of fasting bears, which bear has been fasted for two weeks or more, said composition having a molecular weight of 100 or less, which composition, when injected into a mammal other than a bear, which mammal has been ovariectomized, produces by comparison to an ovariectomized mammal not treated with said composition of matter, enhanced bone growth.

No references are relied on by the examiner as the basis of the pending rejection.

Grounds of Rejection

Claims 63-65 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement.

Claims 1-21, 24-30, 44-45 and 63-66 stand rejected under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-33, 49 and 51 are rejected under 35 USC § 101 as being a substantial duplicate of claims 31, 48 and 50.

Claim Grouping

Appellants state that regarding the §112, first paragraph rejection, Claims 63-65 stand and fall together and are to be considered as one group.

Regarding the §112, second paragraph, rejection, the appellant has grouped the claims as standing or falling together according to the phrases determined by the examiner to be indefinite:

- A) "chemistry similar to"
- B) "ursus-like"
- C) "resembling the characteristics of a bear derived isolate"¹
- D) "comprising"²
- E) "at least one vital sign of behavioral modification substance" and "other substances"
- F) "signature exhibited in the deproteinated isolate of urine or blood"
- G) functional language
- H) "substance"
- I) "metabolites"

Therefore, we decide this appeal on the basis of claim 63 as representative of claims 63-65; claim 10 as representative of claims with the language "chemistry similar to". Claims 4, 13 and 44-45 are treated individually. Claim 1 is representative of claims having functional language.

Background

The pending claims relate to a composition of matter which is a deproteinated isolate comprising certain pharmacological properties and which is a deproteinated isolate which has been obtained from a sample of urine or serum from a fasting bear

¹ Claim 2 was amended by Paper No. 4, filed May 8, 1998 to delete the phrase "resembling" and replacing it with the language "chemistry similar to".

² This rejection does not appear in the examiner's Answer.

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from which food has been withheld for two weeks or more, which sample has been subjected to deproteinization. The deproteinized isolate has the pharmacological properties of inducing, when injected into another animal, conditions observable in denning black bears including reduced heart rate, temperature reduction, or a tranquility distinguishable from normal behavior. Specification pages 30 and 111. Appellant consistently refers to the composition which has been deproteinized as bear derived isolate (BDI). Specification, pages 8 and 12-14.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejection, we make reference to the examiner's Answer for the examiner's complete reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. Paper No. 4, filed May 8, 1998 is of record as having been entered into the application.

This appeal is related to pending appeals in Serial No. 08/440,320 (Appeal No. 1999-1312) and Serial No. 08/461,065 (Appeal No. 2001-1743). We have considered these related appeals together with the appeal in the present application. As a consequence of our review, we make the determinations which follow.

35 U.S.C. §112, first paragraph

Claims 63-65 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement.

An analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contained sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. In order to establish a prima facie case of lack of enablement, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). See also In re Morehouse, 545 F.2d 162, 165, 192 USPQ 29, 32 (CCPA 1976). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

The examiner argues that the specification is enabling for a composition comprising a deproteinated fasting bear serum or urine and the fractions disclosed in the specification, but it does not reasonably provide enablement for a pharmacological composition comprising 24, 25 dihydroxyvitamin D3 or a composition having a molecular weight of 100 or less. The examiner states that the specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the invention commensurate in scope with the claims. Answer, page 3. In particular, the examiner argues that the active ingredients responsible for bone formation are not clear, especially in view of the "wide and varied quantity and quality of the components of the individual fractions of the deproteinated serum or urine. One skilled in the art would be unable to predict that isolation of merely the above referenced components would result in a composition having the desired stimulation of bone formation." Answer, page 4.

With respect to pending claim 63, we find no reasonable explanation on the part of the examiner as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. While the examiner raises reasonable concerns regarding the language "or a composition having a molecular weight of 100 or less" in claim 64, this language is not present in claim 63. Thus with respect to claim 63, the examiner has not met the initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention and, thus, has not established a prima facie case of lack of enablement.

With respect to claims 64 and 65, on pages 7 and 10 of the Brief appellants argue that they have cancelled claims relating to the molecular weight of 100 or less, i.e., Claim 64. However, we find no paper of record providing for cancellation of claim 64. Moreover, claim 65 remains pending in the application and is dependent upon claim 64. The examiner's Answer, page 3, also confirms the pending status of claim

64. Therefore, claims 64-65 are pending and include the claim language "or a composition having a molecular weight of 100 or less".

It appears from language in the Brief that appellants' intention was to delete this language from the claims. In addition, appellants have not contested this aspect of the examiner's enablement rejection. Accordingly, the rejection of claims 64-65 under 35 U.S.C. §112, first paragraph for lack of enablement is affirmed. The rejection of claim 63 under 35 U.S.C. §112, first paragraph for lack of enablement is reversed.

35 U.S.C. §112, second paragraph

Claims 1-21, 24-30, 44-45 and 63-66 stand rejected under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Whether a claim is indefinite depends upon whether those skilled in the art would understand what is claimed, or the scope or the bounds of the claim, when read in light of the specification. The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning of claim indefiniteness.

"Chemistry similar to"

The examiner argues that certain of the claims are indefinite due to the presence of the language "chemistry similar to". We agree with the examiner that the specification fails to define and reasonably convey to one of ordinary skill in the art how similar in chemistry a product must be to have a "chemistry similar to" a concentrate of deproteinated sample (claim 19) or "chemistry similar to" a fraction of the aqueous portion of blood or urine taken from a fasting bear ... (claim 15).

Definiteness problems often arise when words of degree are used in a claim. "That some claim language may not be precise, however, does not automatically render a claim invalid. When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree. The trial court must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification." Seattle Box Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-4 (Fed. Cir. 1984). The term "similar" in the preamble of a claim has previously been found by this Board to be indefinite. Ex parte Kristensen, 10 USPQ2d 1701 (Bd. Pat. App. & Int. 1989).

In the absence of discussion in the specification indicating the criteria or degree of similarity required for determining chemical similarity, in our view, one of ordinary skill in the art would not readily understand what is claimed when the claims are read

in light of the specification. The rejection of claims containing this language is sustained.

Functional Language

The examiner argues that claims 1-15 and 18 include functional language, and that there is no way to determine the required characteristics of the compared isolate. Answer, page 5. The examiner argues that "if the composition is not characterized in a chemical manner, how can one skilled in the art compare it chemically to any other composition." Id.

However, appellants may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the Court in In re Swinehart, 439 F.2d 210, 212-213, 169 USPQ 226, 228-229 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

The examiner argues the phrase "having the characteristics" (claims 10-11), fails to describe the composition, as it is unclear what characteristics the phrase encompasses, such that the metes and bounds of the claims are clear. Answer, page 4.

Appellant responds, arguing that one of ordinary skill in the art reading the phrase would understand its meaning and further that case law suggests that the meaning of the term "characterized" is equivalent to that of the term "comprising", citing, Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1282, 230 USPQ 45, 47 (Fed. Cir. 1986).

In the present case, the full phrase in question is, "having the characteristics of deproteinated urine or serum of a fasting bear".³ The specification indicates on page 12, that Bear Derived Isolate (BDI) may be found both in the serum and urine of denning black bears. Page 21 of the specification provides a description of a purification process of BDI from urine. Urine is deproteinated by centrifugation and BDI collected in the supernatant. The term "deproteination" is specifically defined in the specification on page 3 as, "subject of the sample to any of various procedures for removing all or part of the original protein in the sample."

As stated in In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963), "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same." The substance which results from a

³ It is well settled that "[t]ransitional phrases such as ... 'having' ... must be interpreted in light of the specification to determine whether open or closed language is intended." Lampi Corp. v. American Power Products Inc., 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000); Manual of Patent Examining Procedure §2111.03 (7th ed. rev. 2000); see also Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (construing term "having" as permitting inclusion of other entities).

deproteination of bear urine and serum and the characteristics of that substance appears to be what is claimed. The specification describes several characteristics of deproteinated serum and urine or BDI. BDI, for example, includes Miers-Nelson Component (MNC). Properties of MNC appear on page 24-26 of the specification. Other characteristics of BDI discussed in the specification are the ability to induce signs of tranquility, reduce heart rate, and reduce body temperature in animals receiving BDI. Specification, page 30. Thus, it would appear that the specification describes deproteination, and the resulting product in a manner which would be understood by those of ordinary skill in the art.

Similarly, we find no indefiniteness with the phrase "having the characteristics of an isolate of whole blood or whole urine sample" in the claims. Claims using this language define the isolate product in terms of a specific process of purification and deproteination. See claims 16 and 17. When these claims are read as a whole, they would appear to define a specific product with reasonable clarity to be understood by those of ordinary skill in the art.

"Ursus-like"

As to the term "ursus-like" as used in the claims, we agree with the examiner that the specification fails to properly define the metes and bounds of this term. During ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re

Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Thus, if we interpret the term "ursus-like" pharmacologic compound as used in the claims to encompass something more than a compound obtained from the bear species, the question then becomes, What additional subject matter is covered by the claims?

While appellant would argue that "one wishing to practice the invention need to look no further than the disclosure to obtain the meaning of the term", the appellant has failed to direct our attention to any disclosure in the specification other than that referring to bears or black bears, such as the North American Black Bear, Ursus Americana. Brief, page 13. It remains unclear as to what additional subject matter is encompassed by the claim language "ursus-like".

This is another instance in which claim definiteness problems arise due to a word of degree used in a claim. Again, when a word of degree is used the court must determine whether the patent's specification provides some standard for measuring that degree. The court must decide whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.

We remind appellant that it is appellant's burden to precisely define the invention, not the PTO's. In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997). In the present case, appellant has failed to make the intended meaning of the term "ursus-like" in the claims before us explicitly clear in the specification. Without an express definition of the term "ursus-like" in the specification, it is not known what subject matter is encompassed by the term.

Moreover, appellant has failed to provide evidence to support the position that one of skill in the art would understand the claim term.

Accordingly, the rejection of claims 2, 14, 18, and 21 under 35 USC § 112, second paragraph for indefiniteness of the term "ursus-like" is affirmed.

"Metabolites"

The examiner argues that the term "metabolites" in claims 4 and 13 is indefinite, but presents no analysis as to why the term is considered to be indefinite. Answer, page 4. We further note that the term "metabolites" was deleted from claim 4 in Paper No. 4.

As to claim 13, Appellants define the term "metabolites" on page 4 of the specification as "any of various inorganic or organic compounds produced by metabolic pathways in the body such as urea, creatinine, amino acids, hydroxy acids, fatty acids, glucose, ions, etc." Page 56 of the specification indicates that BDI may be used "alone or in combination with metabolites of denning bears which are also found in humans."

In our opinion the examiner has not provided sufficient evidence that one of ordinary skill in the art reading the present specification would fail to understand which metabolites in humans are present in denning bears as set forth in claim 13.

"Signature marker exhibited in the deproteinized isolate of urine or blood"

The examiner additionally argues that claim 13 is indefinite because "it is unclear what is meant by the term "signature [marker] exhibited in the deproteinized isolate of urine or blood." Answer, page 5. Appellants argue that the term "signature" is defined as set forth in the American Heritage Dictionary, Second College Edition, as "a distinctive mark, characteristic or name." Appellants argue that the deproteinized isolate of claim 13 "must include the signature BDI in order to produce its effects." Brief, page 15. However, arguments of counsel cannot take the place of evidence. In re DeBlauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984), In re Payne, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979).

Appellant has not directed our attention to anything in the specification which refers to BDI as the signature marker found in deproteinized bear serum or urine referred to in claim 13. Nor, in our opinion, is such a reference to BDI obtained from a review of the specification, as a whole. The term "signature marker" is a broad term which remains undefined in the specification. For this reason, we find that one of ordinary skill in the art would fail to understand what is claimed, or the scope or the bounds of the claim, when read in light of the specification.

"Vital sign of behavioral modification substance"

The examiner also finds the phrase, "evidence of at least one vital sign of behavioral modification substance" in claim 4, to be indefinite. Answer, page 4.

The examiner states that "claims 4-8 merely claim 'evidence' of a substance present in the blood or urine of a fasting bear; what is comprised by this 'evidence' is totally unknown." Answer, page 9.

Contrary to the position of the examiner, we find more difficulty with the phrase "vital sign of behavioral modification substance" than with what would constitute appropriate evidence of a vital sign modification or behavioral modification substance as determined by one of ordinary skill in the art.

At first blush, the terminology, on its face, is confusing and nonsensical. Although engaging in speculation, in order to make sense of this language in the claim, it would appear that the term "of" should be replaced with the term "or", and that the confusion in the phrase may have resulted from a typographical error in the claim.

Appellants do not, however, argue that there is error in the claim, and instead argue that behavioral modification properties, such as tranquility are discussed on page 30 of the specification. This argument, however, does not explain the confusion arising from the nonsensical phrase, "vital sign of behavioral modification substance". We find that those skilled in the art would not understand what is

claimed, or the scope or the bounds of the claim, when read in light of the specification, and thus the rejection for indefiniteness is sustained.

"Substance"

The examiner finds the term "substance" in claims 12-15 and the term "active substance" in claims 44 and 45 to be indefinite. Answer, pages 4-5. The appellants indicate that the term "substance" was a typographical error and request that they be allowed to amend the claims 44 and 45. Brief, page 16. Appellants appear to accede to the rejection, as they offer no argument in rebuttal to the rejection. The rejection of claims 44 and 45 is sustained.

Claims 12-15 were amended in Paper No. 4 to delete the term "substance". The rejection of these claims due to the language "substance" is reversed.

35 USC § 101

Claims 32-33, 49 and 51 are rejected under 35 USC § 101 as being a substantial duplicate of claims 31, 48 and 50.

The examiner states that "When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k)." Answer, page 9. The examiner appears to allege that several of the claims in a single application

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are duplicative and thus present double patenting issues. The examiner relies on 35 U.S.C. § 101, double patenting as the statutory basis of the rejection.

The question to be resolved in determining whether an obviousness-type double patenting rejection is proper is set forth in In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970) is: Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? The duplicate claims in the present application do not meet this criteria and, thus, are not tantamount to double patenting.

As stated in MPEP 706.03(k), claims may be objected to under 37 CFR 1.75 (b) which prohibits claims from being unduly multiplied. The principles applicable to this situation are well established.

... applicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged. Such latitude, however, should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion. The rule of reason should be practiced and applied on the basis of the relevant facts and circumstances in each individual case.

In re Flint, 411 F.2d 1353, 1357, 162 USPQ 228, 230 (CCPA 1969); in In re Chandler, 319 F.2d 211, 225, 138 USPQ 138, 148 (CCPA 1963).

In the present case, we find there to be minor variations in the claim language, such that the claims are not identical. We do not find the claims to be unduly multiplied, in a manner which would render the claims confusing or indefinite. Nor do

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we find any basis for a double patenting rejection. The rejection for double patenting is reversed.

CONCLUSION

The rejection of claims 63 under 35 U.S.C. §112, first paragraph for lack of enablement is reversed. The rejection of claims 64-65 under 35 U.S.C. §112, first paragraph for lack of enablement is affirmed.

The rejection of claims 1, 16, 30, 63 and 66 under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is reversed.

The rejection of claims 2-15, 17-21, 24-29, 44-45 and 64-65 under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is affirmed.


The rejection of claims 32-33 and 49 under 35 USC § 101, double patenting, as being a substantial duplicate of claims 31, 48 and 50 is reversed.

As a result of our action today claims 1, 16, 30-33, 49-51, 63 and 66 are free of rejection.

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No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART


Sherman D. Winters
Administrative Patent Judge


Toni R. Scheiner
Administrative Patent Judge


Demetra J. Mills
Administrative Patent Judge

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